RESEARCH PROTECTIONS UPDATE

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Establishing a Human Research Protection Program Standard Operating Procedure Process within an Institution

By Phi Ngo and Lorena Lynch, Naval Health Research Center

In 2022, the Naval Health Research Center (NHRC) Human Research Protection Program (HRPP) had a 100% turnover of staffing within a few months. New HRPP staff had little to no training and were unable to provide prompt guidance to their science investigators about HRPP procedures. HRPP staff realized that their ability to support the researchers was being affected by a lack of Standard Operating Procedures (SOPs). The NHRC HRPP implemented an SOP development process intended to provide reference materials and guidance to both science investigators and future HRPP staff.

Before drafting SOPs, the HRPP Department collected best practices from regulations, training materials, and subject matter experts. HRPP staff built a standardized template to structure SOPs, including sections for Purpose, Procedure Workflow, References, and Forms. Weekly check-in meetings were held to discuss questions, review drafts, and plan next steps. The Microsoft Teams platform was used for document control and collaborative editing. Using these methods, seven SOPs were developed in seven months, including but not limited to: The Institutional Review Board (IRB) Pre-Review, Data Use Requests, Post-Approval Monitoring, Data Breach Reporting, Social Security Number Use and Justification, and Final Data Disposition.

By tracking metrics of IRB submissions and average turnaround times, the HRPP Department found that the average total volume of submissions to the HRPP office each month increased after the distribution of SOPs. However, the average number of business days a submission spent with both the study team and the IRB staff decreased over time. The time that an IRB submission spent with either the study team for edits or the IRB staff for review decreased from over 20 business days to under 10 business days after SOPs were distributed.

By collaborating on an SOP development process, HRPP staff at NHRC were able to provide guidance without the time and effort of multiple training sessions. SOPs foster an efficient collaboration between researchers and HRPP staff. More efficient IRB processing of submissions allows the HRPP office to better facilitate research at an institution.

ESTABLISHING A HUMAN RESEARCH PROTECTION PROGRAM SOP
PROCESS WITHIN AN INSTITUTION
VOLUME OF IRB SUBMISSIONS BY MONTH
TIME SPENT WITH STUDY TEAM VS. IRB

From left to right: Lorena Lynch, HRPP Administrator and Phi Ngo, IRB Chair, Human Research Protection Official, and HIPAA Privacy Officer

DON HRPP Spotlight

Ms. Stephanie Hoyer has been a Compliance Specialist at the Department of the Navy (DON) HRPP since June 2022. In her current role, she provides comprehensive support and guidance regarding human research regulations and compliance. She serves as the DON HRPP point of contact for the Naval Health Research Center, the Naval Submarine Medical Research Laboratory, the U. S. Naval Medical Research Unit INDO PACIFIC, and the Naval Medical Leader and Professional Development Command.

Prior to joining DON HRPP, Stephanie was a Clinical Research Associate at the Naval Medical Center San Diego (NMCSD) where she gained experience working in Navy research. Before working at NMCSD, she worked at Scripps Health in Interventional Cardiology Clinical Trials. Stephanie has over 7 years of experience working in the medical and research fields. She earned her Bachelor of Arts degree in Psychology at Queens University of Charlotte in North Carolina.

CITI FAQs

- **What is Collaborative Institutional Training Initiative (CITI)?** CITI provides training courses for staff working in organizations involved in human subjects research (HSR), including exempt, expedited, and full board IRB-approved studies. The DON uses CITI to fulfill HSR training requirements.
- **How do I access CITI?**
  Visit: https://about.citiprogram.org
- **Who should complete the CITI training?** All DON personnel who engage in, and review, HSR.
- **How do I know what courses to take?** Researchers and research personnel should select courses that correspond with the type of research they're conducting/reviewing and their exact role. Refer to the Minimum Education Requirements for Department of Defense (DoD) Personnel Involved in Human Research Protection (MERF, 2012) for additional information.
- **What if I already completed CITI at another institution?** Organizations may allow learners to receive credit for modules previously taken. Learners may receive credit for required Navy CITI modules they recently completed at other institutions.
- **When does my CITI training expire?** Training expires after 3 years and must be retaken.
- **How long does it take to complete CITI training?** Most modules take 15-30 minutes to complete. The full training program course could take 3-6 hours.

EDO Module Added to CITI

The Exemption Determination Official (EDO) module is now available in CITI. It aims to familiarize EDOs with specific requirements of DoD-conducted research involving human subjects. The module is designed to simplify complex decision-making processes and provide EDOs with knowledge and tools to make informed determinations, ensuring compliance with ethical and regulatory standards.

For more information and to enroll in the CITI EDO course, visit: https://about.citiprogram.org.

DON HRPP CLaSS

DON HRPP held its Command Learn and Share Series (CLaSS) session on 25 March 2025. The session focused on Post-Approval Compliance Monitoring (PACM), highlighting the crucial role of ongoing oversight in ensuring the ethical and safe conduct of HSR. Ms. Terri Brantley of the Naval Medical Research Command and Ms. Christina Ramirez of the United States Marine Corps Manpower & Reserve Affairs shared best practices and unique PACM approaches implemented by their HRPPs. The session drew strong interest, with 59 participants representing 20 commands across the DON enterprise, furthering their commitment to ethical human research. A recording of the session is available upon request from the DON HRPP.

A huge thank you to Ms. Brantley and Ms. Ramirez who were instrumental to the session's success and we appreciate their participation.

More CLaSS Ahead!

We are excited to announce the lineup for the next CLaSS sessions. Stay tuned for dates and times for each session.

Managing Research Noncompliance: Identification, Correction, Prevention, and Reporting

This CLaSS focuses on practical strategies for managing research noncompliance. Guest presenters will share their expertise, providing a detailed overview of noncompliance review processes within their respective human research protection programs.

Navigating the Survey Review Process

The objective of this CLaSS is to gain a better understanding of the submission, review, and approval processes for research-related surveys administered within the DON. To maximize the scope and Q&A segment of this session, please submit questions with subject line "Survey Review Process CLaSS Question" to usn.pentagon.cnr-arlington-va.mbx.onr-343@us.navy.mil.

Have a "Good News" story or best practice you want to share? Please send your research news, success stories, tips, pictures, lessons learned, or other material related to the ethical conduct of human research to DON HRPP.

The RESEARCH PROTECTIONS UPDATE is published by the Department of the Navy Human Research Protection Program.
Email: usn.ncr.bumedfchva.mbx.don-hrpp@health.mil ** Telephone: (703) 681-9629